REMARKS

In order to place this application in condition for allowance or to provide the claims in a form more suitable for consideration on appeal, the applicant has cancelled claims 55, 56, 61-67, 82-92 and 95, without prejudice, and added claims 96 and 97.

As defined in claim 93, the present invention provides a bioerodible implant for treating an inflammation mediated condition of the eye in an individual, which implant consists of an anti-inflammatory agent and a bioerodible copolymer and is structured to be placed in the vitreous of the eye. The implant is an extruded filament, having a weight between 500 ug and 1000 ug ~~about~~ and releasing at least about 20% of the agent within about 20 days in vitro.

As set forth in new claims 96 and 97, said filament has a diameter of between 650 and 790 mm. and a length of between 0.94 and 1.97 um.

The Examiner has rejected claims 93-95 under 35 USC 112, first paragraph. The Examiner finds that Examples 6 and 7 enable the formulations disclosed therein, but do not enable the broad subject matter defined by claims 93 through 95. (Claim 95 has been cancelled.)

In particular, the Examiner has objected to the range of weights claimed for the filaments of this invention. The applicants have amended claims 93 and 94 to recite the actual weights of the filaments tested in the examples. (See page 27, lines 10 and 11 of the specification.)

Thus, the applicants disagree with the Examiner on this issue. The implants of Examples 6 and 7 are 500 ug and 1000 ug. This surely supports a claim, as now amended, of from 500 ug to 1,000 ug.

In an effort to further remove the Examiner's rejection under 35 USC 112, the applicant has added new claims 96 and 97. Such claims further limit the implants of claims 93 and 94 by specifically incorporating the dimensions of the implant filament. (See Example 6 of the specification wherein said filament has a diameter of between 650 and 790 mm. and a length of between 0.94 and 1.97 um.)

The Examiner has rejected claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-95 under 35 U.S.C. 103(a) as being unpatentable over Wong (U.S. patent 5,869,079).

Applicants have responded to the rejection of claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-92, as set forth in the previous Office Action in the last response. Applicants choose to continue to rely on their arguments made in such response. (Note, the applicants have cancelled claims 55-56,61-67, 82-92 and 95, without prejudice, solely to put the claims in better condition for consideration on appeal, as explained below.) However, the Examiner has rejected claims 93-95 for the first time in the Final Rejection. Thus, applicants respond to this new rejection as follows:

The Examiner argues that the only difference between the implant of Example 1 of Wong and the implants of claims 93-95 is that the weights of the claimed implants are greater.

The Examiner dismisses applicant's argument that it is surprising that a larger weight drug delivery device would have the same release rate as a smaller weight drug delivery device. The Examiner states: "this is not surprising if the drug delivery device is a filament. If it were a sphere, yes, it would be surprising, but not with a filament." The Examiner goes on to add that the "filament has a much more constant surface area to volume ratio as the length..... increases."

The applicants believe the Examiner is wrong and that it is, indeed, surprising that the filaments of Examples 6 and 7 as compare with the filaments of Example 1 of Wong have similar release rates, despite the fact that the surface area to volume ratio of Wong is much greater. A comparison the filaments of Examples 6 and 7 with the filaments of Example 1 of Wong is made as follows:

The applicants have utilized filaments in Examples 6 and 7 having the following dimensions:

"The PLGA/dexamethasone mixture was mixed well, the blend loaded into a barrel, and 650-790 μm diameter filaments extruded. The resulting filaments were cut into lengths of approximately 0.94 and 1.87 mm for the 500 μg and 1000 μg formulations, respectively."

The diameter of the filaments of Examples 6 and 7 compare with the filaments of Wong, which are described in Example 1 of Wong as being extruded through a 20 gauge orifice is calculated as follows:[1]

AMERICAN WIRE GAUGE	**WIRE DIAMETER IN INCHES**
20	0.03196118

The conversion of the diameter in inches to um is as follows:

0.03196118 X 25.4 mm/inch X 1000 um/mm = 812 um

Thus, the diameters of the filaments of Example 1 of Wong are substantially equal to the filaments of Examples 6 and 7 of the present patent application.

The surface area of a cylinder (filament) is calculated as follows:

$A = 2(\pi)r^2 + 2(\pi)rh$ wherein r=radius and h is height or length

The volume of a cylinder is calculated as follows:

$V = (\pi)r^2h$

1. To determine the diameter of a filament extruded through a 20 gauge orifice, one is referred to the WIRE GAUGE TABLES of RBE Electronics, which is submitted herewith.

Thus, the surface area to volume of a cylinder is calculated as follows:

$A/V = 2(\pi)r^2 + 2(\pi)rh/ (\pi)r^2h$ or $\mathbf{2(r^2 + rh)/r^2h}$

Assuming that r is about 400 um for all of the filaments, i.e. the filaments of Example 1 of Wong and Examples 6 and 7 of the present patent application, the equation becomes:

$A/V = 2((400)^2 + 400h)/(400)^2h$ or $\mathbf{320000 + 800h/160000h^2}$

Since, the filaments of Examples 6 and 7 of the present patent application are 500 or 1000 ug (.94 and 1.87 mm, in length, respectively,) and the filaments of Wong are about 100 to 120 ug (which is about 1/5 of the 500 ug filament of Examples 6 and 7) the length of the filaments of Wong is calculated to be about 0.2. And, since the diameter of the Wong filaments are substantially the same as the filaments of Examples 6 and 7, above, the A/V for each may be calculated thus:

Example 6 (500 ug)

A/V = 3200 + 8 (.94)/ 1600 $(.94)^2$ or **2.3**

Example 6 (1000 ug)
A/V = **0.5**
Wong

A/V = 3200 + 8 (.2)/ 1600$(.2)^2$ or **50**

Thus, it is clear that the A/V of Wong is substantially greater than the A/V of the present invention and yet "(t)he 100-120 ug 50/50 PLGA/dexamethasone implant disclosed in U.S. Patent No. 5,869,079 shows similar *in vitro* release kinetics to the 500 and 1000 ug 50/50 PLGA/dexamethasone implant disclosed herein. However, the previously disclosed implant would not provide drug concentrations in the vitreous at the levels described herein." (See the conclusion of the description of the present invention as set forth in the specification at pages 30 and 31.)

In view of the above, it is believed that the claimed implants (drug delivery devices) show surprising properties and therefore even if the Examiner's prima facie case for obviousness is correct, (which the applicants do not accept) the inventions defined by claims 94 and 95 are patentable.

Since this amendment is submitted after final rejection, the following should be considered:

According to 37 CFR 116 (MPEP 714.12) an amendment after final is proper in the following circumstances:

"(1) An amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action;

(2) An amendment presenting rejected claims in better form for consideration on appeal may be admitted; or

(3) An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented."

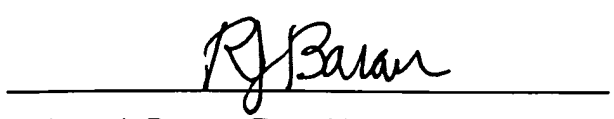
As to (1) above, this amendment cancels claims 55, 56, 61-67 and 82-95.

Clearly, amending claims 93 and 94 to recite the actual weight of the implant tested, overcomes the rejection under 35 USC 112 and, therefore, removes one issue from the appeal and also presents the "rejected claims in better form for consideration on appeal". (See (2), above.)

As to (3) the Examiner raised the issue of the surface area/volume for the first time in the Final Rejection. Therefore, this reponse is timely.

In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectfully requested.

Respectfully submitted,



Date: July 18, 2008

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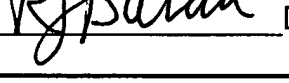
Signature:  Date July 18, 2008

RBE Electronics

WIRE GAUGE TABLES

American Wire Gauge (AWG) sizes may be determined by measuring the diameter of the conductor (the bare wire) with the insulation removed. Refer to the Wire gauge Diameter Table for dimensions. When choosing wire gauge, the distance the wire must run and the amperage it will be expected to carry must be determined first. Refer to the Wire gauge Selection Table. Note that you can always use thicker wire (lower gauge number) than is recommended.

METRIC-TO-AWG CONVERSION TABLE	
Metric Size mm2	AWG Size
0.5	20
0.8	18
1.0	16
2.0	14
3.0	12
5.0	10
8.0	8
13.0	6
19.0	4
32.0	2
52.0	0

WIRE GAUGE DIAMETER TABLE	
American Wire gauge	Wire Diameter in inches
20	0.03196118
18	0.040303
16	0.0508214
14	0.064084
12	0.08080810
10	0.10189
8	0.128496
6	0.16202
5	0.18194
4	0.20431